

REMARKS

The foregoing amendments and the following remarks are submitted for entry and consideration in connection with the Request for Continued Examination submitted herewith and in response to the communication dated October 28, 2008.

Status of the Claims

Claims 14-17 and 33-35 are previously pending and examined in the application. Claims 14-17 and 33-35 have been canceled, without prejudice and new claims 37-51 are now presented in order to more particularly point out and distinctly claim that which Applicants regard as the invention. With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications. No new matter is added by the amendment of the claims or in the newly presented claims.

Support for the new claims can be found generally through Applicants' specification. Applicants direct the Examiner to the specification generally, including the claims as filed. Particular support for the language of the newly presented claims includes for example the claims and page and line numbers as set out as follows:

Claim 37 is supported throughout the specification, including at least in original claims 1 and 14 and at page 9 lines 5-7, page 11 lines 28-31 and page 165 lines 29-32.

Claim 38 is supported throughout the specification, including at least at page 76 lines 24-26 and Table 1 page 80.

Claim 39 is supported throughout the specification, including at least in original claim 2 and at page 9 lines 13-14.

Claim 40 is supported throughout the specification, including at least in original claim 3 and at page 9 lines 16-23.

Claim 41 is supported throughout the specification, including at least in original claim 7 and at page 12 lines 1-7, page 160 lines 20-27, page 161 line 26 through page 162 line 7, page 163 line 18 through page 164 line 20, and page 165 lines 4-11.

Claim 42 is supported throughout the specification, including at least at page 3 lines 12-27, page 25 lines 15-26, and page 82 line 14 through page 83 line 2.

Claim 43 is supported throughout the specification, including at page 25 lines 1-19 and page 165 lines 14-18.

Claim 44 is supported throughout the specification, including at least at page 16 lines 17-19, Figure 33, page 32 lines 20-24, page 161 lines 10-13, and Table 6.

Claim 45 is supported throughout the specification, including at least in original claim 15 and at page 12 lines 9-15.

Claim 46 is supported throughout the specification, including at least in original claim 15 and at page 12 lines 9-15, page 16 lines 17-19, page 19 lines 1-2 and lines 10-11, Figure 33, page 32 lines 20-24, page 161 lines 10-13, and Table 6

Claim 47 is supported throughout the specification, including at least in original claim 16 and at page 12 lines 17-19.

Claim 48 is supported throughout the specification, including at least in original claim 8 and at page 10 lines 6-10 and page 12 lines 17-19.

Claim 49 is supported throughout the specification, including at least in original claim 11 and at page 10 lines 6-14.

Claim 50 is supported throughout the specification, including at least in original claim 10 and at page 10 lines 13-14 and page 12 lines 17-19

Claim 51 is supported throughout the specification, including at least at page 161 lines 9-13, Table 6, and Figure 33.

Claim Rejections - 35 U.S.C. 112, First Paragraph – New Matter

Claims 14-17 and 33-35 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection is set out as a new matter rejection, the Examiner alleging that the recitation that the stem cells do not form tumors in an animal is considered new matter because there is no description in the Specification for a pluripotent embryonic-like stem cell with the limitations claimed. Applicants respectfully traverse this rejection. Applicants respectfully disagree and submit that the rejected claims comply with the written description requirement. Further, Applicants have above canceled claims 14-17 and 33-35 without prejudice to further prosecution, and without acquiescing to the rejections set forth by the Examiner. As rejected claims 14-17 and 33-35 have been canceled, Applicants respectfully submit that this rejection is moot and should properly be withdrawn. Applicants assert that newly presented claims 37-51 fully comply with the written description requirement and do not contain new matter.

In view of the foregoing remarks and amendments, Applicants submit that the Examiner's written description rejection under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

Claim Rejections - 35 U.S.C. 112, First Paragraph – Enablement

Claims 14-17 and 33-35 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner argues that the claims broadly encompass isolated pluripotent cells, including from any species, and that the characterization Applicants' cells are pluripotent is not predictable. Additionally, the Examiner alleges that the cells express markers that fail to uniquely identify embryonic stem cells, because these markers are expressed in other cell types. Applicants respectfully disagree and submit that rejected claims 14-17 and 33-35 are fully enabled. Applicants again assert that the instant stem cells are new, novel, and unique from any stem cells, embryonic-like (ES) or otherwise, in the prior art. Applicants have above canceled claims 14-17 and 33-35 without prejudice to further

prosecution, and without acquiescing to the rejections set forth by the Examiner. As rejected claims 14-17 and 33-35 have been canceled, Applicants respectfully submit that this rejection is moot and should properly be withdrawn. New claims 37-51 are presented and are particularly directed to isolated postnatal animal stem cells capable of self-renewal and capable of differentiation to cells of endodermal, ectodermal and mesodermal lineages. Applicants submit that new claims 37-51 comply with the 35 U.S.C. 112, first paragraph, enablement requirement.

In view of the foregoing remarks and amendments, Applicants submit that the Examiner's enablement rejection under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

Claim Rejections - 35 U.S.C. 112 – Written Description

The Examiner again rejects claims 14-17 and 33-35 as failing to comply with the written description requirement, alleging that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The Examiner asserts that the specification fails to provide sufficient, identifying characteristics of the claimed cells such that one of skill in the art would recognize that Applicants had possession of the claimed cells. Applicants respectfully traverse this rejection. Applicants argue that the rejected claims 14-17 and 33-35 provide identification and characterization of the claimed cells to establish and uniquely identify the instant stem cells. Applicants have above canceled claims 14-17 and 33-35 without prejudice to further prosecution, and without acquiescing to the rejections set forth by the Examiner. As rejected claims 14-17 and 33-35 have been canceled, Applicants respectfully submit that this rejection is moot and should properly be withdrawn. Applicants assert that newly presented claims 37-51 comply with the written description requirement and contain subject matter which was described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s) had possession of the invention at the time the application was filed.

In view of the foregoing remarks and the above amendments, Applicants submit that the Examiner's 112, first paragraph, rejection regarding new matter is obviated and should be withdrawn.

Claim Rejections – 35 USC § 112, Second Paragraph

Claims 14-17 stand rejected under 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner asserts that claims 14 and 15 remain unclear in the term “not totipotent”. Applicants respectfully traverse this rejection and assert that the rejected language is clear. Applicants have above canceled claims 14-17 without prejudice to further prosecution, and without acquiescing to the rejections set forth by the Examiner. As rejected claims 14-17 have been canceled, Applicants respectfully submit that this rejection is moot and should properly be withdrawn. Applicants assert that newly presented claims 37-51 are definite and clear, and point out that the rejected recitation is not present in the new claims. Applicants respectfully submit that the language of new claims 37-51 is clear and definite and request that the claim rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

The §103 Rejections

The Examiner has maintained her rejection of claims 14-17 as unpatentable under 35 U.S.C. 103(a) over Shamblott [PNAS 95:13726-13731 (1998)] when taken with Sambrook et al [Molecular Cloning, Book 3, 1989]. The Examiner has cited Shamblott et al. as teaching the generation of human pluripotent stem cells from gonadal ridges and mesenteries containing primordial germ cells (PGCs) and teaching that embryoid bodies collected from these cultures revealed a wide variety of differentiated cell types, including derivatives of all three embryonic germ layers. The Examiner asserts that the claims do not provide any requisite characteristics of the claimed stem cells such that they would be distinguished from the cells taught by Shamblott. Applicants respectfully traverse this rejection and again assert that the claimed pluripotent stem cells are distinguished from the Shamblott PGC cells and are not rendered obvious by the

combination of the Shablott and Sambrook references. Shablott's PGCs are absolutely distinct and do not anticipate, or make obvious, Applicant's pluripotent stem cells. The addition of or combination of Sambrook to Shablott's cells does not serve to make Applicant's cells or method of isolating them obvious. Applicants have above canceled claims 14-17 without prejudice to further prosecution, and without acquiescing to the rejections set forth by the Examiner. As rejected claims 14-17 have been canceled, Applicants respectfully submit that this rejection is moot and should properly be withdrawn. Applicants assert that newly presented claims 37-51 are patentable and non-obvious over Shablott when taken with Sambrook et al.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's 103 rejection is obviated and may properly be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Should the Examiner feel that further issues remain upon a review of this Response, she is invited to call the undersigned at the number listed below to effect their resolution. Early and favorable action on the claims is earnestly solicited.

No additional fees are believed to be necessitated by this response, however, in the event the U.S. Patent and Trademark office determines that claim fees, a further extension and/or other relief is required, applicant petitions for any required relief including extensions of time and claim fees and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 11-1053** referencing Docket No. 1304-1-019CIP.

Respectfully submitted,

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